WHAT IS CLAIMED IS

~~CLAIMS:~~

1. An isolated pathogenic *Leptospira* bacterium which belongs to serogroup Hurstbridge or serovar hurstbridge as hereinbefore defined or a derivative bacterium thereof which is serologically cross-reactive to a bacterium belonging to serogroup Hurstbridge or serovar hurstbridge.

2. The isolated pathogenic *Leptospira* bacterium according to claim 1, wherein said bacterium exhibits the growth characteristics of *Leptospira* strain WKID (AGAL Accession No. N95/69684) or *Leptospira* strain BUT6.

3. The isolated pathogenic *Leptospira* bacterium according to claim 2, wherein said bacterium is capable of growing in media containing at least 100µg/ml 8-azaguanine.

4. The isolated pathogenic *Leptospira* bacterium according to claims 2 or 3, wherein said bacterium is capable of growing at temperatures in the range from about 13°C to about 37°C.

5. The isolated pathogenic *Leptospira* bacterium according to any one of claims 1 to 4, wherein said bacterium is a pathogen which is capable of infecting a human or a livestock animal or a companion animal selected from the list comprising pigs, bovines, sheep, goats, horses, deer, alpaca, dogs and cats.

6. The isolated pathogenic Leptospira bacterium according to claim 5, wherein said bacterium is capable of infecting pigs.

7. The isolated pathogenic Leptospira bacterium according to claim 5, wherein said bacterium is capable of infecting humans.

8. The isolated pathogenic Leptospira bacterium according to claim 5, wherein said

bacterium is capable of infecting bovines.

9. The isolated pathogenic Leptospira bacterium according to any one of claims 5 to 8, wherein said bacterium is capable of producing the symptoms of leptospirosis in a human or other animal which it infects.

10. The isolated pathogenic Leptospira bacterium according to any one of claims 1 to 8, wherein said bacterium is capable of inducing reproductive disease.

11. The isolated pathogenic Leptospira bacterium according to claim 10, wherein the reproductive disease induced by said bacterium comprises reduced farrowing.

12. The isolated pathogenic Leptospira bacterium according to claim 10, wherein the reproductive disease induced by said bacterium comprises foetal death *in utero* or spontaneous abortion.

13. The isolated pathogenic Leptospira bacterium according to claim 10, wherein the reproductive disease induced by said bacterium produces an increased weaning-to-mating period in the offspring of an infected animal.

14. The isolated pathogenic Leptospira bacterium according to claim 10, wherein the reproductive disease induced by said bacterium comprises seasonal infertility.

15. The isolated *Leptospira* bacterium according to any one of claims 1 to 14, wherein said bacterium further contains nucleic acid which is at least about 80% identical to the nucleotide sequence set forth in any one of SEQ ID NOs:1-2 or 4-7 or a homologue, analogue or derivative thereof comprising at least 15 contiguous nucleotides which are at least about 80% identical to the nucleotide sequence set forth in said SEQ ID NOs. or a complementary nucleotide sequence thereto.

16. The isolated *Leptospira* bacterium according to any one of claims 1 to 14 wherein said bacterium further comprises a rRNA gene sequence which is at least 80% identical to the nucleotide sequence 5′-TGTTGGA-3′ or at least 90% identical to the nucleotide sequence 5′-TTTGATA-3′ or a homologue, analogue or derivative thereof or a complementary nucleotide sequence thereto.

17. The isolated *Leptospira* bacterium according to claim 16 wherein the rRNA gene sequence comprises a nucleotide sequence which is at least 85% identical to the nucleotide sequence 5′-TGTTGGATCACAAGATTTGATA or a homologue, analogue or derivative thereof or a complementary nucleotide sequence thereto.

18. The isolated *Leptospira* bacterium according to any one of claims 15 to 17 wherein the percentage identity is at least about 97%.

19. The isolated pathogenic *Leptospira* bacterium according to any one of claims 1 to 18 having the characteristics of the microorganism deposited under AGAL Accession No. N95/69684 or which is serologically cross-reactive thereto.

20. An isolated *Leptospira* bacterium deposited under AGAL Accession No. N95/69684.

21. A method of isolating the *Leptospira* bacterium according to any one of claims 1 to 20, said method comprising the steps of:

(i) collecting tissue from a human or other animal subject infected therewith;

(ii) homogenising said tissue in a suitable homogenisation medium for a time and under conditions sufficient to release said bacterium from said tissue whilst maintaining the integrity of said bacterium; and

(iii) culturing the homogenised tissue in a suitable culture medium for a time and under conditions sufficient to allow said bacterium to grow.

22. The method according to claim 21, wherein the culture medium is EMJH medium.

23. The method according to claim 21 or 22, wherein the culture medium is supplemented with 8-azaguanine or 5-fluorouracil.

24. The method according to any one of claims 21 to 23, wherein the culture medium is supplemented with at least one antibiotic.

25. The method according to claim 24, wherein the antibiotic is selected from the list comprising rifamycin, macrolide polyene and quinoline or a derivative compound thereof.

26. The method according to any one of claims 21 to 25, wherein the culture conditions comprise growth in the temperature range from about 13°C to about 37°C.

27. The method according to any one of claims 21 to 26 wherein the other animal subject is a livestock animal or a companion animal.

28. The method according to claim 27, wherein the livestock animal or companion animal is selected from the list comprising pigs, bovines, sheep, goats, horses, deer, alpaca, dogs and cats.

29. The method according to claim 28, wherein the livestock animal is a pig.

30. The method according to any one of claims 21 to 29, wherein the tissue is blood, serum, plasma, urine, cerebrospinal fluid, liver, lung or tissue derived from the urogenital tract selected from the list comprising bladder, kidney, uterus or fallopian tube or testes.

31. The method according to claim 30, wherein the tissue is kidney or urine.

32. An antibody molecule which is capable of binding to the isolated *Leptospira*

bacterium according to any one of claims 1 to 20 or an antigen derived from said bacterium.

33. The antibody molecule according to claim 32, further defined as a polyclonal antibody molecule.

34. A method of diagnosing the presence of the pathogenic *Leptospira* bacterium according to any one of claims 1 to 20 in a biological sample derived from a human or other animal subject, said method comprising contacting said biological sample or a nucleic acid molecule derived therefrom with one or more isolated probes or primers comprising a nucleotide sequence set forth in any one of SEQ ID Nos:2-7 or a homologue, analogue or derivative thereof or a complementary sequence thereto for a time and under conditions sufficient for hybridisation to occur and then detecting said hybridisation using a detecting means.

35. The method according to claim 34, wherein the detecting means is a reporter molecule which is bound to the isolated nucleic acid molecule probe.

36. The method according to claim 35, wherein the reporter molecule is a radioisotope or biotin.

37. The method according to claim 34, wherein the detecting means is a polymerase chain reaction.

38. The method according to claim 37, wherein the polymerase chain reaction employs at least one primer comprising a nucleotide sequence set forth in SEQ ID NO:2 or SEQ ID NO:3 or a derivative thereof.

39. The method according to claim 37, wherein the polymerase chain reaction employs two primers comprising the nucleotide sequences set forth in SEQ ID NOS:2 and 3 or a derivative of any one of said nucleotide sequences.

40. The method according to any one of claims 37 to 39 comprising a nested PCR wherein:

(i) the first amplified gene sequence obtained from a first round of amplification is contacted with one or more second nucleic acid primers of at least about 15 nucleotides in length derived from the nucleotide sequence set forth in SEQ ID NO:1 or a complementary sequence thereto capable of hybridising at a position in said first amplified gene sequence which is internal to the position of the nucleic acid primer sequence(s) used to generate said first amplified gene sequence; and

(ii) copies of said first amplified gene sequence are amplified using PCR to produce a second amplified product comprising *Leptospira* serovar hurstbridge or serogroup Hurstbridge rRNA gene sequences.

41. The method according to any one of claims to 37 to 40, comprising the further step of sequencing the amplified nucleic acid molecule product.

42. A method of diagnosing the presence of the pathogenic *Leptospira* bacterium according to any one of claims 1 to 20 in a biological sample derived from a human or other animal subject, said method comprising contacting said biological sample with an antibody molecule that binds to said bacterium or an antigen thereof for a time and under conditions sufficient for an antibody:antigen complex to occur and then detecting said complex using a detecting means.

43. A method of diagnosing a past or present infection of a human or other animal subject by the pathogenic *Leptospira* bacterium according to any one of claims 1 to 20, said method comprising contacting a biological sample such as blood, serum, or a derivative thereof derived from said human or animal subject with said pathogenic *Leptospira* bacterium or an antigen derived therefrom for a time and under conditions sufficient for an antibody:antigen complex to occur and then detecting said complex using a detecting means.

44. The method according to claims 42 or 43 comprising an immunoassay or serological assay.

45. The method according to claim 44, wherein the immunoassay or serological assay comprises MAT or ELISA.

46. A method of diagnosing the presence of the pathogenic *Leptospira* bacterium according to any one of claims 1 to 20 in a human or other animal subject, said method at least comprising the steps of culturing cells or tissue derived from said subject under selective culture conditions which are specific for said bacterium for a time and under conditions sufficient to allow said bacterium to grow.

47. The method according to claim 46, wherein the selective culture conditions comprise growth at a temperature in the range from about 13°C to about 37°C on a culture medium supplemented with 8-azaguanine or 5-fluorouracil.

48. The method according to claim 47, wherein the culture medium is supplemented with at least one antibiotic.

49. The method according to claim 48, wherein the antibiotic is selected from the list comprising rifamycin, macrolide polyene and quinoline or a derivative compound thereof.

50. The method according to any one of claims 34 to 49, wherein the other animal subject is a livestock animal or a companion animal.

51. The method according to claim 50, wherein the livestock animal or companion animal is selected from the list comprising pigs, bovines, sheep, goats, horses, deer, alpaca, dogs and cats.

52. The method according to claim 51, wherein the livestock animal is a pig.

53. The method according to claim 51, wherein the livestock animal is a bovine animal.

54. The method according to any one of claims 34 to 53, wherein the biological sample comprises a homogenate or tissue or cell extract or whole cells or tissues derived from serum, blood, urine, cerebrospinal fluid, liver, lung, bladder, kidney, uterus, fallopian tube or testes.

55. The method according to claim 54, wherein the tissue is the biological sample comprises a homogenate or tissue or cell extract or whole cells or tissues derived from serum, blood, urine or kidney.

56. A diagnostic kit for the detection of the pathogenic *Leptospira* bacterium according to any one of claims 1 to 20 in a human or other animal subject or a biological sample derived therefrom, said kit at least comprising a first compartment which contains one or more immunogens derived from said pathogenic *Leptospira* bacterium and a second compartment which contains an antibody molecule that binds to said bacterium or an antigen thereof.

57. A diagnostic kit for the detection of the pathogenic *Leptospira* bacterium according to any one of claims 1 to 20 in a human or other animal subject or a biological sample derived therefrom, said kit at least comprising a first compartment which contains two non-complementary nucleic acid primer molecules of at least about 15 nucleotides in length comprising a nucleotide sequence set forth in any one of SEQ ID NOS:2-7 and a second compartment which contains a reaction buffer suitable for the performance of a nucleic acid hybridisation reaction or polymerase chain reaction.

58. A composition which is capable of conferring protective immunity against the pathogenic *Leptospira* bacterium according to any one of claims 1 to 20 in a human or animal subject, said composition comprising an attenuated form of said pathogenic *Leptospira* bacterium or one or more isolated or recombinant immunogens which are

immunologically cross-reactive with a cellular component thereof and one or more pharmaceutically or veterinarially acceptable carriers, adjuvants and/or diluents.

59. The composition according to claim 58, wherein the attenuated form of the pathogenic *Leptospira* bacterium is a killed bacterium or a killed bacterial culture.

60. The composition according to claim 58 or claim 59, wherein the pathogenic *Leptospira* bacterium is present at a concentration of at least about 10^8 organisms per unit dose.

61. The composition according to claim 58, wherein the adjuvant comprises aluminium hydroxide.

62. A composition which is capable of conferring protective immunity against the pathogenic *Leptospira* bacterium according to any one of claims 1 to 20 in a human or animal subject, said composition comprising serum derived from a human or other animal which is infected with said pathogenic *Leptospira* bacterium or a derivative product of said serum and one or more pharmaceutically or veterinarially acceptable carriers, adjuvants and/or diluents, wherein said serum or derivative comprises antibodies which are capable of binding to the pathogenic *Leptospira* bacterium or to one or more immunogens thereof.

63. The composition according to claim 62 wherein the serum or a derivative product thereof is capable of producing a MAT titre of at least about 256.

64. A method of prophylactic or therapeutic treatment of infection of a human or animal subject by a pathogenic *Leptospira* bacterium of serogroup Hurstbridge or serovar hurstbridge or a serologically cross-reactive derivative thereof, said method comprising administration of the composition according to any one of claims 58 to 63 to said human or animal subject for a time and under conditions sufficient to induce an immune response in said subject.

65. The method according to claim 64 wherein the immune response is a humoral immune response.

66. A method of prophylactic or therapeutic treatment of leptospirosis in a human or animal subject comprising administration of the composition according to any one of claims 58 to 63 to said subject for a time and under conditions sufficient for said subject to resist a subsequent challenge by a pathogenic *Leptospira* bacterium of serogroup Hurstbridge or serovar hurstbridge or a serologically cross-reactive derivative thereof.

67. A method of prophylactic or therapeutic treatment of reproductive disease in a human or animal subject comprising administration of the composition according to any one of claims 58 to 63 to said subject for a time and under conditions sufficient for said subject to resist a challenge by a pathogenic *Leptospira* bacterium of serogroup Hurstbridge or serovar hurstbridge or a serologically cross-reactive derivative thereof.

68. The method according to claim 67, wherein the reproductive disease is associated with seasonal infertility, reduced farrowing, foetal death *in utero* or spontaneous abortion in the infected subject or with increased weaning-to-mating period in the offspring of the infected subject.

69. The method according to any one of claims 64 to 68, wherein the composition is administered by injection.

70. The method according to any one of claims 64 to 69 wherein the subject being treated is a human.

71. The method according to any one of claims 64 to 69, wherein the subject being treated is a livestock animal or a companion animal.

72. The method according to claim 71 wherein the livestock animal or companion

animal is selected from the list comprising pigs, bovines, sheep, goats, horses, deer, alpaca, dogs and cats.

73. The method according to claim 72, wherein the livestock animal is a pig.

74. The method according to claim 72 wherein the livestock animal or companion animal is a bovine animal.